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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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ALSTRUM ACEVEDO, JAMES HENRY	
ART UNIT	**PAPER NUMBER**
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/646,362	ZENG, XIAN-MING	
	Examiner	Art Unit	
	James H. Alstrum-Acevedo	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 8-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 8-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/7/07; 7/2/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-6 and 8-15 are pending. Applicants have cancelled claim 7. Applicants have amended claims 1-6 and 8-10. Claims 11-15 are new. Receipt and consideration of Applicants new IDS (submitted 7/2/07 and 9/7/07), amended claim set, and remarks/arguments, submitted on July 2, 2007 are acknowledged.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Moot Rejections/objections

All rejections and/or objections of claim 7 cited in the previous office action mailed on October 30, 2006 **are moot**, because said claim has been cancelled.

Specification

The objection of claims 2-6 and 8-10 because of the informalities set forth in the previous office action **is withdrawn** per Applicants' amendments correcting said informalities.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement (new matter). The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant specification does not support particulate carrier with mean particle sizes ranging from about 89 to about 110 in diameter. The instant specification only has written support for a dry powder inhalation composition according to claim 9 wherein the MDPI is capable of producing 12 mcg dose having a fine particle fraction (FPF) of 49-54% or a 6 mcg dose having a FPF of 48% not about 49-54% nor about 48% (see the Table 2 on page 11 of the specification). The specification does not support claims 14-15, wherein the compositions comprise any active and exhibit the supported FPF values. The specification only supports compositions consisting of formoterol fumarate and lactose and exhibiting the FPF values disclosed in Table 2 on page 11.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 is indefinite due to the recitation of a derivative of formoterol. The 10th edition of the Merriam-Webster's Collegiate Dictionary (Merriam-Webster Incorporated: Springfield,

Massachusetts, 1993, pp 311) defines "derivative" as, "a chemical substance related structurally to another substance and theoretically derivable from it." For example, carbon dioxide could theoretically be derived from the combustion of formoterol. Therefore, the definition of derivative in the Merriam-Webster Collegiate Dictionary does not shed light on what Applicants' intended for the meaning of a formoterol derivative.

Claim 11 is vague because the particle size range recited in claim 11 has no units of measurement; thus, it is unclear what range is being claimed. Appropriate correction is required.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1-2 and 5-10 under 35 U.S.C. 102(b) as being anticipated by Haeberlin (WO 01/39745) **is maintained** for the reasons of record and further articulated below.

Response to Arguments

Applicant's arguments filed 7/2/07 have been fully considered but they are not persuasive. Applicants have traversed the instant rejection by asserting that the amount of active agent disclosed by Haeberlin allegedly does not touch the range claimed by Applicants (i.e. allegedly the amount disclosed by Haeberlin is 0.249% vs. Applicants' required minimum of 0.25%).

The Examiner respectfully disagrees with Applicants' traversal argument, because when fairly comparing calculated numerical values it is imperative that one utilize the same number of

significant figures. Applicants' claimed minimum is only recited to two significant figures, thus it is inappropriate to calculate a figure for the prior art and report it using three significant figures. When Applicants' calculation is repeated and limited to two significant figures, the prior art value touches Applicants' claimed range. Thus, the instant rejection is deemed to remain proper.

The rejection of claims 1-7 under 35 U.S.C. 102(b) as being anticipated by Keller (WO 00/28979), wherein U.S. Patent No. 6,645,466 is being used as the English language equivalent **is withdrawn** per Applicants' claim amendments to utilize "consisting of" language.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 1-6 and 8-10 under 35 U.S.C. 103(a) as being unpatentable over Haeberlin (WO 01/39745) **is maintained** for the reasons articulated below. Claims 11-15 are appended to this rejection. Thus, **claims 1-6 and 8-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haeberlin (WO 01/39745)** for the reasons of record and further articulated below.

Response to Arguments

Applicant's arguments filed 7/2/07 have been fully considered but they are not persuasive. Applicants have traversed the instant rejection by asserting that it is not reasonable to optimize the maximum amount of formoterol disclosed by Haeberlin to higher values.

The Examiner respectfully disagrees with Applicants' traversal argument. Regarding the previously stated optimization of the amount of formoterol, this statement is retracted. It would have been well within the capability of the ordinary skilled artisan to adjust the amount of active

agent in a dry powder formulation per the needs of subjects in need of treatment and said subjects' response to treatment. Furthermore, the modification of the amount of active in a composition is an obvious way to increase the amount of active agent administered to a subject as well as modifying the amount of a given active agent administered. Applicants have not demonstrated any particular criticality regarding the amount of active agent present in the claimed composition. Applicants have not asserted that amounts of active greater than 0.25% w/w yield unexpected or surprising results or that compositions comprising amounts of active below 0.25% w/w exhibit undesirable properties. Applicants' general statements in paragraph [0008] are not persuasive as to the alleged superior properties of the claimed composition, but merely represent unsubstantiated allegations of superiority. Regarding the FPF fractions recited in claims 14-15, Haeberlin is silent. Applicants are reminded that the Office lacks laboratory facilities to test the compositions invented by Haeberlin to determine the FPF that these would exhibit upon administration from an IVAX® MDPI, as was used by Applicants in their determination of the FPF of their invented formoterol fumarate dihydrate compositions.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225

USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The provisional rejection of claims 1, 4-7, and 9 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 9-11 of copending Application No. 10/646,361 (copending '361) in view of Haeberlin (WO 01/39745) **is maintained** for the reasons of record and because Applicants did not traverse the instant rejection with any substantive arguments.

Conclusion

Claims 1-6 and 8-15 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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